

TRE Legal Toolkit



TRE/SDE Legal Toolkit

- Clearly define roles and responsibilities between data custodians, data processors and researchers
- Standardised templates for data access, data sharing agreements and DPIAs.



Potential benefits:

- Enable researchers to fill out a single DPIA form rather than multiple ones
- Speed up contracting within universities and research institutions
- Transparent and easy to understand Toolkit built with PPIE

TRE Legal Toolkit - Components

Data Depositing
Agreement (DDA)

Data Access
Agreement (DAA)

Data Protection
Impact
Assessment
(DPIA)

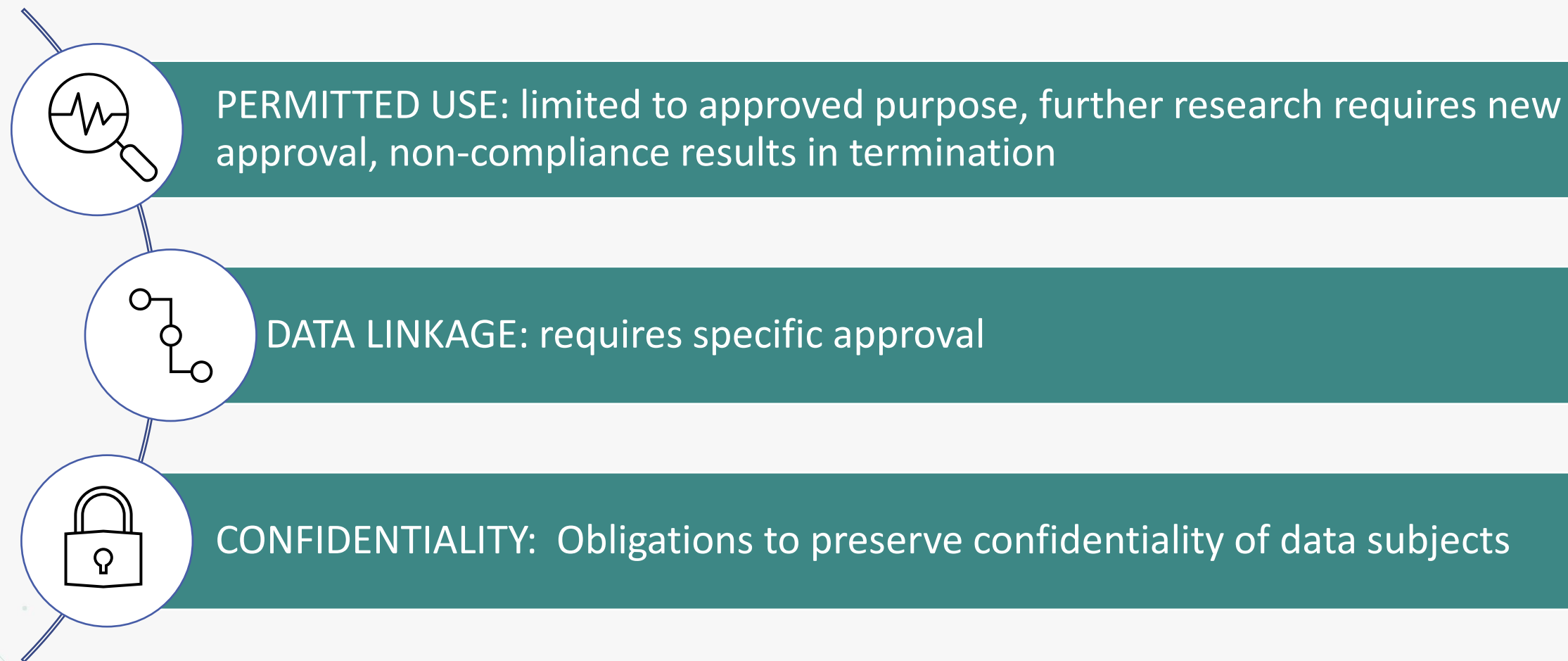
Guidance

Patient and Public Involvement & Engagement (PPIE)

Benefits of cross-custodian collaboration

- Rapid development technically and legally
 - ICO anonymisation guidance
 - NHS TRE accreditation framework
 - Technical developments around SDEs
 - Existing SDE contracting may not reflect latest requirements
- Evolution of researcher needs
 - Common approaches to enable data linkage to create rich data sets across the four nations
- Involving public and patients to ensure legal arrangements are transparent, clear and meet public and patient expectations to build trust
- Forum for sharing experiences, jointly developing best practice, making recommendations to sector

DAA – Similarities



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IP OWNERSHIP: no transfer of ownership



RE-IDENTIFICATION: prohibited (although linkage may be permitted)

DAA – Differences



FORMAT: scattered between different documents e.g. order form, data access agreement, end user terms, security policy, dissemination policy etc



PARTIES: user, institution, or both

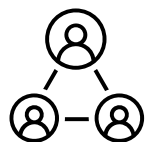


COMMERCIAL USE: prohibited, permitted if part of access request, or permitted subject to subsequent approval

DAA – Differences



OUTPUT APPROVAL: notification or output checking



ROLES OF PARTIES: not always explicitly defined (independent controller, joint controller, processor)



USER SECURITY REQUIREMENTS: e.g whether VPN required

DAA – Differences

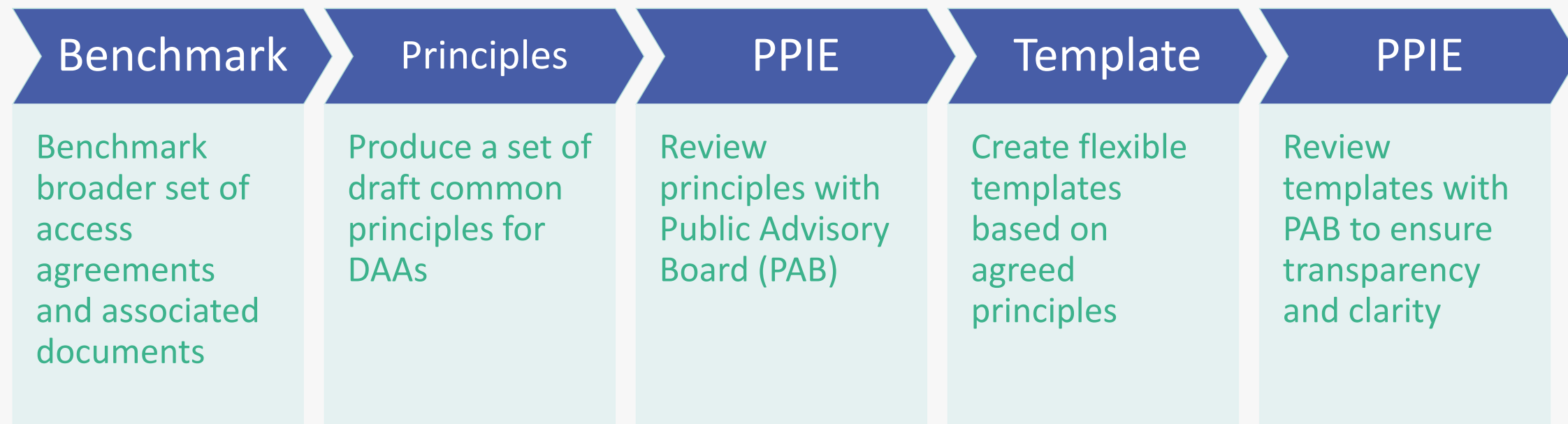


TECHNICAL SECURITY REQUIREMENTS: for institution e.g. ISO certifications



TRAINING/ACCREDITATION FOR USER: scope, content and frequency of re-accreditation vary

DAA – next steps...



Then DDA, DPIA, guidance...

Questions:

- Do you think the toolkit has the right components? Anything to add?
- Do you think the toolkit will help speed up the contracting process?
- What else do we need to consider for this to work?